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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,062	02/20/2004	Charles Thomas Cunnyngnam	P06298US02 - PHI 1467	7826

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MCKEE, VOORHEES & SEASE, P.L.C.
ATTN: PIONEER HI-BRED
801 GRAND AVENUE, SUITE 3200
DES MOINES, IA 50309-2721

EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/784,062	CUNNINGHAM, CHARLES THOMAS	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2202004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Request under 37 CFR 1.105</u> |

DETAILED ACTION

Priority

1. In the priority statement in lines 9-12 of page 1 of the specification, the status of U.S. application 10/271,065 should be updated to recite the patent number that issued from it.

Information Disclosure Statement

2. The IDS filed February 20, 2004 contains a PTO-891 that was mailed by the USPTO during prosecution of parent application 10/271,065. The information listed in that form has been considered in the instant application. However, this is not a proper form 1449. Applicants should submit a form 1449 listing the references cited on the 891 form.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-6 and 13-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,759,580 ('580). Although the conflicting claims are not identical, they are not patentably distinct from each other because: Instant claim 1 is drawn towards any seed comprising at least one set of chromosomes of maize inbred line PH87H. This claim encompasses seed of PH87H itself, as well as F1 hybrid progeny that have PH87H as one parent. Patented claim 1 anticipates instant claim 1, since it is directed to the inbred seed of line PH87H. Instant claims 2 and 3 are drawn to a maize plant, or a part thereof, produced by growing the seed of claim 1. Patented claim 2 is drawn to the plant produced by growing PH87H seed, and a part of said plant. Instant claims 4-5 are drawn to an F1 hybrid maize seed produced by crossing PH87H with a different maize plant, and a F1 hybrid plant and part thereof produced by growing said F1 hybrid seed. Patented claim 8 is drawn towards a method of producing an F1 hybrid maize seed, comprising crossing a plant of line PH87H with a different maize plant and harvesting the resultant seed. It would have been obvious to one of ordinary skill in the art to grow seed produced by the method of patented claim 8 to yield the F1 hybrid plant. One would have been motivated to do so to use the F1 hybrid plant in further crosses, to produce new maize varieties, for example. Further, the method of patented claims 25 and 30 comprise producing and further crossing F1 hybrid plants that have PH87H as one parent. Instant claim 13 is drawn to a maize plant having all morphological and physiological characteristics of PH87H. Patented claim 24 is drawn to a maize plant, or part thereof, that has all the physiological and morphological characteristics of PH87H, and therefore

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anticipates instant claim 13. Patented claim 2 also anticipates instant claim 13, as instant claim 13 encompasses the plant of inbred line PH87H itself. Instant claim 14 is drawn to a method of crossing the plant of claim 13 with itself or another maize plant to form seed. This process is anticipated by the method of patented claim 8. Instant claims 15-16 are drawn towards seeds that are formed by carrying out the process of instant claim 14, and growing the resultant seed to produce a hybrid plant. Instant claim 18 is directed to maize seed produced by growing the maize plant of claim 17 and harvesting the resultant seed. It would have been obvious for one of ordinary skill in the art to grow the seed produced by patented claim 8, and produce the hybrid plant, and to use it in further crosses. One would have been motivated to do so to produce further desirable maize lines. Instant claim 19 limits the plant of claim 13 by requiring it to comprise the SSR profile in Table 4. The plant of patented claim 2, which is PH87H, inherently possesses this SSR profile. Instant claim 20 is drawn to a cell of the plant of claim 13 and instant claim 21 requires it to have the SSR profile in Table 4, which is anticipated by patented claims 2 and 24, which inherently have this same SSR profile. Instant claim 22 is drawn to a seed comprising the cell of claim 20, which is anticipated by patented claim 1. Instant claim 23 limits the plant of instant claim 13 by requiring it to have a genome comprising a single locus conversion. "Single locus conversion" is discussed on page 32 of the specification. Given this discussion, patented claims 26-29 and 31 are plants that anticipate instant claim 23. Instant claim 24 requires the single locus of the plant of claim 23 to be stably inserted by transformation. The plant of patented claim 28 comprises a bacterial gene, which inherently was inserted into a maize genome by transformation. Instant claim 25 requires the single locus of the plant of claim 23 to be a dominant or recessive allele. The bacterial gene in the plant of patented claim 28 can

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be considered a dominant allele. Instant claim 27 limits the plant of claim 13 by further requiring it to comprise a gene conferring male sterility. Instant claim 28 further limits the plant of claim 13 by further requiring it to comprise a transgene that confers male sterility, herbicide resistance, insect resistance, or disease resistance. This is anticipated by patented claims 10, 12, 13, 15, 16, and 18, which are plants produced by transforming PH87H with transgenes that confer these traits. The steps of the method of instant claim 29 are anticipated by the methods of patented claims 25 and 30. Instant claim 30 requires the plant produced by claim 29 to be an inbred, and instant claim 31 further limits the method of claim 30 by crossing the inbred with a second, distinct inbred plant to produce an F1 hybrid maize plant. It would have been obvious to self the plant produced by patented claims 25 or 30 to produce an inbred. One would have been motivated to do so to produce a true breeding maize line having desired traits. It would have been further obvious to cross that inbred with another inbred plant, to produce F1 hybrids. One would have been motivated to do so, for the purpose of producing yet more new varieties of maize having desirable traits. One Instant claim 32 is drawn towards a method for developing a maize plant in a breeding program using the plant, or parts thereof, of claim 13. Instant claim 33 limits the method of claim 32 by reciting several breeding techniques, including backcrossing and transformation. Patented claims 9, 11, 14, 17, 19, 21, 25, and 30 each anticipate instant claims 28 and 29, as they encompass a method of transforming PH87H or a method that involves backcrosses. Instant claims 28 and 29 do not indicate when the methods are finished, that is, when the plant is developed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 24, 26, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 24: the article, "a" in the recitation, "the single locus was stably inserted into a maize genome by transformation" renders the claim indefinite. It is unclear if the genome is that of the plant of claim 13, or another plant.

In claim 26: the recitations, "yield enhancement", "improved nutritional quality", and "male sterility and male fertility" render the claim indefinite. The terms "yield enhancement and "improved nutritional quality" are relative and have no definite meaning. Regarding "male sterility and restoration of male fertility": it is unclear what trait is being conferred by this. If the trait of male sterility is being conferred, then this would be reversed by restoration of male fertility. What, then, is the resultant phenotype? If this recitation is actually supposed to be two separate Markush group members, then it is confusing because the specification does not define the plant of claim 13 as being male sterile. Introduction of a trait restoring male fertility would not change anything in the recipient plant. The metes and bounds of the claim are unclear.

In claim 33: the preamble of the claim indicates that the method is for developing a maize plant in a maize plant breeding program using plant breeding techniques. However, the claim does not indicate when the maize plant is developed. It is unclear when the method ends. The metes and bounds of the claim are unclear.

In claim 34: the recitation, "the molecular marker profile" renders the claim indefinite. There is insufficient antecedent basis for the recitation in the claim.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn towards any maize seed produced by growing a hybrid maize plant, wherein the hybrid maize plant was produced by crossing a maize plant having all the morphological and physiological characteristics of maize plant PH87H with a second maize plant. As the maize seed of claim 18 is produced by growing the hybrid maize plant, and harvesting the resultant seed, the claimed seed is two generations removed from the plant having the characteristics of PH87H.

The specification teaches several morphological and physiological characteristics of PH87H in Table 1. A deposit of seed of PH87H has also been made with the ATCC under accession number PTA-4688, in accordance with 37 CFR 1.801-1.809. All F1 hybrid seed produced from PH87H inherit one set of chromosomes from PH87H. This structure is shared with every F1 hybrid. However, when the F1 hybrid is again outcrossed, the next generation will not inherit the haploid genome of PH87H. The genome of the next generation of plants will not share the same structure as the haploid genome of PH87H, or the set of chromosomes of the F1 hybrid inherited from PH87H. There will therefore be wide variability in the genomic structure

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of the claimed maize seeds. The instant specification does not describe the structure of a single second generation maize seed, or any functions (morphological and physiological traits) possessed by the claimed seed. The specification does not disclose a single species of the genus of seeds encompassed by claim 18. Given the breadth of the claims encompassing second generation descendants from the plant of claim 13, and the absence of a description of a single such seed, and the variability that exists among the species of the claimed genus, it is submitted that the specification fails to provide an adequate written description of the multitude of maize seeds encompassed by the claim.

7. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is drawn towards an F1 hybrid maize seed comprising an inbred maize plant cell of inbred maize line PH87H. There is no written description support for such a seed, or plant produced therefrom, in the specification. The claim and those dependent thereon contain NEW MATTER and must be cancelled.

8. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

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the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 is drawn towards an F1 hybrid maize seed comprising an inbred maize plant cell of inbred maize line PH87H. However, the specification does not enable any such seed or plant grown therefrom. By definition, a hybrid seed cannot comprise a single cell that contains a homozygous genome. Not a single F1 hybrid that has PH87H as a parent could have inherited two sets of chromosomes from PH87H, or contain a single cell that has two sets of chromosomes from PH87H. Neither the specification nor prior art teach how to make any such hybrid seed. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make the claimed invention.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 18 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson (U.S. Patent No. 5859355, issued January 12, 1999).

The claim is broadly drawn towards any maize seed, produced by growing a hybrid maize plant and harvesting the resultant seed, wherein the hybrid maize plant was produced by growing seed that was produced by crossing the plant of claim 13 with any second maize plant.

Johnson et al. teach hybrid maize seeds (claims; col. 28, line 1 to col. 31, line 14). The seed may have been produced from a method different from those of the instantly claimed seed. However, the instantly claimed products do not appear to differ from the products taught by the reference. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The instant claim does not recite any limitation(s) that distinguishes the product from that of the reference.

10. Claims 1-34 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner’s supervisor, Anne Marie Grunberg, can be reached at 571-272-

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0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

September 25, 2006



Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638

ATTACHMENT TO OFFICE ACTION

Request for Information under 37 CFR § 1.105

1. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. This request is being made for the following reasons:

Applicant is claiming a seed comprising at least one set of the chromosomes of maize line PH87H, PH87H comprising a single locus conversion, seed produced by growing a hybrid maize plant having PH87H as a parent, a plant comprising 95% of the alleles (base pairs) of inbred line PH87H at the SSR loci listed in Table 4. However, the instant specification is silent about what starting materials and methods were used to produce maize line PH87H. The requested information is required to make a meaningful and complete search of the prior art.

3. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(i) What were (are) the original parental maize lines used to produce maize line PH87H?

Please supply all of the designations/denominations used for the original parental maize lines and line PH87H. Please supply information pertaining to the lineage of the original parental lines back to any publicly available varieties.

(ii) What method and method steps were used to produce maize line PH87H?

(iii) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, had any of said parental maize lines or progeny therefrom been disclosed or made publicly available? If so, under what

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designation/denomination and under what conditions were said parental maize lines or progeny disclosed or made publicly available and from when to when?

(iv) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, were any other maize lines produced by said method using said original parental maize lines, and if so, had said produced maize lines been publicly available or sold? If so, under what designation/denomination and under what conditions were said other maize lines disclosed or made publicly available and from when to when?

3. If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

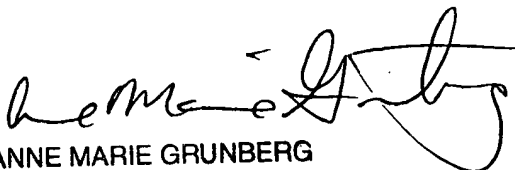
4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please indicate where the relevant information can be found.

5. The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97.

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6. The Applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR § 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

7. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER